

R E M A R K S

As noted in the Office Action Summary, claims 1-53 are canceled and claims 54-97 are pending.

Applicants have amended claims 82-89 and 92 to depend from claim 54. Support for the amendments can be found at least in the claims as filed.

RESPONSE TO RESTRICTION REQUIREMENT & SPECIES ELECTION

In the Office Action, the Examiner sets forth the restriction requirement as follows:

Group I, claims 54-81 and 94-97, “drawn to an expression vector encoding a fusion protein and a method of use thereof for producing a peptide of interest”; and

Group II, claims 82-91 and 93, “drawn to a fusion protein”.

Applicants provisionally elect with traverse the claims associated with **Group I**, *i.e.*, claims 54-81, and 94-97. Applications further provisionally elect with traverse SEQ ID NO: 27 for search purposes.

Applicants respectfully traverse the restriction requirement as set forth in the Office Action. Applicants respectfully submit that the inventions should properly be examined together. Under M.P.E.P. § 803, restriction is proper if the subject matter can be restricted into one of two or more claimed inventions, and these inventions are either independent (M.P.E.P. § 806.04) or distinct (M.P.E.P. § 806.05). The second element for a restriction requirement to be proper is that if ***no serious burden*** exists, then the Office must examine it on the merits, even though it includes claimed independent and distinct inventions. Furthermore, the Office Action does not set forth an explanation of how a search of the claimed invention would be burdensome, let alone a serious burden. Accordingly, Applicants assert that a proper restriction under M.P.E.P. § 803 has not been set forth with regard to the originally presented claims, the elections herein therefore are provisional.

Additionally, Applicants direct the Office’s attention to Annex B of the Administrative Instructions Under the PCT. Example 1 of Annex B is directed to a method of manufacturing a chemical substance X (claim 1) and substance X (claim 2). In Example 1, Annex B sets forth that there would be unity between claim 1 and claim 2. This application is filed under 35 U.S.C. §371. Therefore, unity of invention under the PCT applies. Because the claims of the instant application are analogous process of making/product claims, the finding of lack of unity is improper in view of the Example presented in Annex B.

Applicants further note that amendments have been prepared to claims 82-89 and 92. The amendments result in the product claims depending from the process claims. Applicants note that the product claims have been elected. Applicants assert that should the product claims be found allowable, at the very least, the process claims should be rejoined with the product claims. *See M.P.E.P. §§ 821.04 and 806.05(i).*

Therefore, the restriction should be withdrawn or, at the very least, reconsidered.

Species Election

With respect to the species election, applications provisionally elect **SEQ ID NO: 27** as the species for search purposes only and *with traverse*. Applicants make the election only to be fully responsive to the Official Action.

Applicants assert that the species election requirement is improper. Applicants note that the Office has required Applicants to elect one of SEQ ID NOS: 5, 8, 21, 22, 23, 27, 28, and 70. Applicants note that SEQ ID NOS: 5 and 8 are directed to helper peptides, SEQ ID NOS: 27 and 28 are directed to peptides of interest, and SEQ ID NOS: 21 and 23 are directed to fusion proteins. Thus, to be forced to elect one species, in the event that the Office deems that one species to be obvious, Applicants would be left with the result of a claim that no longer reflects the currently claimed invention, because it would omit two other categories of sequences.

It is *improper* for the Office to refuse to examine that which applicants regard as their invention, unless the subject matter in the claim lacks unity of invention. *In re Harnish*, 631 F.2d 716, 206 U.S.P.Q. 300 (C.C.P.A. 1980); and *Ex parte Hozumi*, 3 U.S.P.Q.2d 1059 (Bd. Pat. App. & Int. 1984). *See also* M.P.E.P. § 803.02. The Office is reminded of *In re Weber*, 580 F.2d 455, 198 U.S.P.Q. 328 (C.C.P.A. 1978), in which the Court articulated the general proposition that:

[A]n applicant has a right to have *each* claim examined on the merits. If an applicant submits a number of claims, it may well be that pursuant to a proper restriction requirement, those claims will be dispersed to a number of applications. Such action would not affect the right of the applicant eventually to have each of the claims examined in the form he considers to best define his invention. If, however, a single claim is required to be divided up and presented in several applications, that claim would never be considered on its merits. The totality of the resulting fragmentary claims would not necessarily be the equivalent of the original claim. Further, since the subgenera would be defined by the examiner rather than by the applicant, it is not inconceivable that a

number of the fragments would not be described in the specification.

In view of the above and similar case law, the Patent Office has set forth a general policy regarding restriction of Markush-type claims in M.P.E.P. § 803.02. The Office has grouped the claims into one group when they form separate groups. Additionally, where a provisional election of a single species is proper prior to examination on the merits, following election, the Markush-type claim should be examined fully with respect to the elected species and further to the extent necessary to determine patentability. M.P.E.P. § 803.02. The M.P.E.P requires that should no prior art be found that anticipates or renders obvious the elected species, in view of the rest of the invention, the search of the Markush-type claim will be extended to non-elected species.

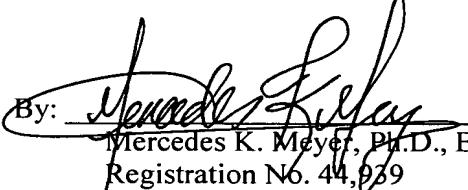
Accordingly, Applicants respectfully request reconsideration of the requested species election and withdrawal of the current species election.

CONCLUSION

In conclusion, this is believed to be in full response to the outstanding restriction requirement. Should any issues remain outstanding or if there are any questions concerning this paper, or the application in general, the Examiner is invited to telephone the undersigned representative at the Examiner's earliest convenience. Should any outstanding fees be owed or overpayments credited, the Commissioner is invited to charge or credit Deposit Account No. 50-0573.

Respectfully submitted,
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